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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,048	12/12/2006	Martin David Bloomberg	056647-0009	4885

46127 7590 05/26/2011

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EXAMINER	
LUDLOW, JAN M	
ART UNIT	PAPER NUMBER
1773	

NOTIFICATION DATE	DELIVERY MODE
05/26/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/570,048	BLOOMBERG ET AL.	
	Examiner	Art Unit	
	JAN LUDLOW	1773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2 and 6-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2 and 6-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 22, 2010 has been entered.

2. The amendment filed June 22, 2010 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: There is no disclosure of citric, acetic or orthophosphoric acid in the disclosure as originally filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

3. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. There is no disclosure of citric, acetic or orthophosphoric acid in the disclosure as originally filed.

5. Claims 2, 6-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention.

1. See below.

2. Claims 2, 6-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

While there is a vague description of extracting grape skins with water, steeping to ferment residual sugar, and evaporation to concentrate and remove alcohol, there is no description of how much water is used, what type of grapes, what mass of grape skins, time and temperature of steeping, resulting volume of extract after evaporation, etc. There is absolutely no description of the cabbage extraction. Therefore, there is not an enabling description of how to make the cabbage extract. In particular, claims 2, 7 are not enabled because there is no way of determining what 27.5 % or 10-27.5% of pH indicator means, since there is no way to reproduce the extraction process. There is ABSOLUTELY NO DESCRIPTION of the process of extracting the cabbage. Is the cabbage crushed and the leached liquid collected? Is there an extracting liquid? If so, how much? Is it then fermented and concentrated by evaporation as in the grape extraction process? The description of extracting the grapes is unclear in and of itself—the juice is removed and then the skins are extracted with an unknown amount of water. Then a steeping process occurs (to the juice or to the skin extract—it's unclear which) to

ferment the sugars to alcohol, and vacuum evaporation is performed to remove alcohol. Since applicant has not disclosed the mass of the grapes or how much water or how much evaporation, there is ABSOLUTELY NO WAY of reproducing this process and to make the same extract as applicant has made, much less any meaningful sense made of a weight basis of a completely undefined extract. For example, extracting 5 g of grape skins with 100 ml of water and concentrating to 80 ml results in a very different extract than extracting 20 g of grape skins with 20 ml of water and concentrating to 5 ml. Further, it is unclear how this process is applicable to red cabbage—is juice removed form the cabbage (to make cabbage juice or wine?) and then the remaining cabbage "skin" extracted with water (again, how much cabbage, how much "skin", how much water?), fermented to make alcohol? And then the alcohol evaporated? The public has absolutely no way of knowing because applicant hasn't disclosed any process for extracting indicator from cabbage whatsoever. Furthermore, the instant disclosure does not enable the range of 10-27.5% for the cabbage extract as in claim 7. The instant disclosure teaches 10-20% (p. 3, last line) for grape extract and then teaches that a higher concentration is required for cabbage extract (p. 4, lines 1-3), but does not teach that 10% is the lower end of the range for cabbage extract. Page 4, penultimate line, enables 27.5% only.

3. Claims 2, 6-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In that there is no description of how the indicator is extracted, it is not clear what "a concentration of …. about 27.5%" means within the concentrate. For example adding 1 part indicator extract having 1 M active ingredient to 9 parts water (about 10%) results in the same composition as adding 5 parts indicator having 0.2 M active ingredient to 5 parts water (about 50%).

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 2, 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fisher (5278132) in view of Freadman (6589761).

Fisher teaches a concentrate having a pH modifying agent and pH indicator, the concentrate having the instant properties, including pH 4-6 indication (col. 4, line 37). Suitable indicators are methyl red, resorcin blue, 2,5-diphenol and chlorophenol red (col. 3, lines 30-32). Acetic, orthphosphoric or citric acid may be added (col. 2, lines 5-10). With respect to claims 6 and 8, the concentrations of the reagents other than the cabbage indicator extract are taught in Example 1.

Fisher fails to teach a naturally occurring pH indicator.

Freadman teaches that a natural food or plant pH indicator from red cabbage or grapes can be used as an alternative to methyl red, resorcin blue, 2,5-Diphenol and chlorophenol red (col. 4, line 61, col. 5, line 30, col. 6, lines 9 and 67, col. 8, lines 49-59).

It would have been obvious to use a cabbage extract indicator in the invention of Fisher because it is an alternative to the indicators of Fisher as taught by Freadman. With respect to claims 2, 7 to the extent that they are definite, it would have been

obvious to optimize the amount of indicator in order to attain the coloration properties taught by Fisher. That is, one of ordinary skill would understand that raw natural extract of cabbage contains a lower concentration of pH indicator than the purified indicator of Fisher, and it would have been obvious to use a greater volume of less pure indicator extract in order to achieve the same result.

9. Applicant's arguments filed June 22, 2010 have been fully considered but they are not persuasive.

10. Applicant argues that one of ordinary skill would know how to prepare a red cabbage extract and cites one method, which once again does not provide a standardized method of producing an extract of reproducible composition. There is an indefinite amount of cabbage, extracted at an unknown temperature in an indefinite amount of solvent, reduced to an unknown volume. Applicant alleges that red cabbage extract is available for purchase, but does not indicate if this is in liquid form, powder form, or of a definite or reproducible composition. Further, there would clearly be plural methods of extracting red cabbage (as explained clearly by the examiner above) and plural available extracts, and applicant has not disclosed which one was used in the claimed quantities.

11. Applicant argues that Freadman does not teach how the red cabbage extracts are produced either, but Freadman teaches that an effective quantity is used; therefore the disclosure is enabling because at whatever concentration of active ingredient in the extract, one of ordinary skill could determine the effective amount to use by adding extract until the desired depth of color is reached.

12. Applicant argues that on page 3 of the instant disclosure, it is disclosed that concentrations of pH indicator of 10-20% were necessary. Page 3 teaches that concentrations of 10% to 20% of **grape extract** were necessary. The statement at the top of page 4 indicates that higher concentrations of cabbage and lichen extract were required. Thus, there is no disclosed lower limit for the concentration of cabbage extract. Higher than 10%? Higher than 20%? How much higher?

13. Applicant argues that "about 27.5%" is clear because it is on a mass/mass basis, but again, fails to address the examiner's arguments regarding the complete lack of disclosure as to how the red cabbage extract is produced—27.5% of an extract having what per cent of active ingredient? An extract having 1% active ingredient at 27.5% concentration produces the same composition as an extract having 2% active ingredient at 13.75% concentration.

14. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

15. One of ordinary skill would have a reasonable expectation of success in substituting one pH indicator for another as taught by Freadman.

16. Applicant argues that typically a concentrate will include red cabbage extract at a concentration of at least 1600 color units of anthocyanin, corresponding to a concentration of 0.02-.2% of red cabbage extract according to a manufacturer, but

provides no reference supporting this allegation. And what if the unknown extract used in the instant invention had an anthocyanin level much lower than the manufacturer's extract? What if, for example, applicant is using a liquid extract and the manufacturer is providing a powdered extract? Likewise, the above admission indicates that even a commercial red cabbage extract varies ten-fold in its anthocyanain concentration batch-by-batch, supporting the examiner's position that the instant concentration is indefinite.

17. Further, the argument that the invention lies in the concentration of the extract is specious in view of the lack of teaching of the method of extraction. Applicant has not addressed the examiner's argument with respect to the clarity of the concentration range:

In that there is no description of how the indicator is extracted, it is not clear what "a concentration of about 10 to about 25%" means within the concentrate. For example adding 1 part indicator extract having 1 M active ingredient to 9 parts water (about 10%) results in the same composition as adding 5 parts indicator having 0.2 M active ingredient to 5 parts water (about 50%).

Since the public has no way of reproducing the instantly alluded to extraction method to make a pH indicator extract having the same concentration of pH indicator as applicant, the concentration of the extract within the concentrate is meaningless.

Applicant argues that while it was known to use cabbage extract as a pH indicator, the color was vary faint and that applicant has determined that a larger concentration of indicator provides a visually detectable color change. This is not an unexpected result. Larger concentrations of colored compounds are expected to provide deeper colors in accordance with Beer's law.

Fisher teaches using an effective amount of indicator for the instant purpose and it would have been obvious to use an effective amount of the alternative natural indicator taught by Freadman. It is within ordinary skill to determine the effective amount.

With respect to claim 9, applicant argues that the claim is supported because the specification states that the formulations of USP 5,278,132 were used, but the patent has not been incorporated by reference, and it is not clear if all possible formulations were tested. The Examples listed in this specification do not include acids. Applicant argues that one of ordinary skill would have expected the acids to degrade the indicator, but provides no evidence to support this statement. To the contrary, Fox teaches producing stable anthocyanins using citric acid (Examples 1, 3) and Vunsh teaches producing stable anthocyanins using acetic acid (col. 4, lines 38-63).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday, Tuesday and Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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